

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG  
CORPORATION, *et al.*

Defendants.

Civil Action No. 3:17-01362

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CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG  
CORPORATION, *et al.*

Defendants.

Civil Action No. 3:17-01665

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**REPLY IN SUPPORT OF DEFENDANTS'  
MOTION TO EXCLUDE THE MARKETING OPINIONS OF ANNA LEMBKE,  
KATHERINE KEYES, ANDREW KOLODNY, AND JAKKI MOHR**

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## INTRODUCTION

Plaintiffs’ marketing theory always has focused exclusively on *manufacturers*—not distributors. With Distributors now the only defendants in this trial, Plaintiffs are maneuvering to keep their marketing theory alive. But, as Distributors explained in their opening papers, Plaintiffs do not have experts who can provide qualified, reliable, and relevant opinions on marketing causation as it relates to Distributors. What Plaintiffs say in their opposition lacks support in the record, is flatly contradicted by the record, or is pure misdirection.

As a threshold matter, three of Plaintiffs’ purported experts—Anna Lembke (a psychiatrist), Katherine Keyes (an epidemiologist), and Andrew Kolodny (a doctor)—are not qualified to opine on marketing. Judge Polster so held with respect to Lembke and Keyes.<sup>1</sup> His analysis applies equally to Kolodny, who likewise lacks any education or experience in marketing. Plaintiffs do not argue that Judge Polster was wrong. Instead, Plaintiffs argue that Judge Polster’s ruling excluded only the experts’ marketing *causation* opinions. But Plaintiffs fail to acknowledge that if the experts are not qualified to opine on marketing causation as it relates to Distributors, then none of the testimony identified in Distributors’ opening papers would be admissible. Incredibly, Plaintiffs also contend that Judge Polster basically reached the wrong conclusion because he did not know any better—he was essentially uninformed about everything Lembke and Keyes reviewed. But Judge Polster knew exactly what Lembke, the psychiatrist, and Keyes, the epidemiologist, did to prepare to offer opinions in the litigation—and he concluded that “a person does not become an expert in an area outside of her regular field merely by ‘reading up’ for the specific purpose of testifying.” MDL Ruling at 11 n.5.

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<sup>1</sup> *In re: National Prescription Opiate Litig.*, MDL 2804, Case No. 1:17-md-2804, Doc. 2549 at 1 (N.D. Ohio Aug. 28, 2019) (“MDL Ruling”) (Exhibit \*).

Lembke, Keyes, and Kolodny—as well as Plaintiffs’ other marketing expert, Jakki Mohr—also failed to use a reliable methodology to opine that Distributors’ so-called marketing activities affected prescribing for opioids. None of them did *anything* to determine if doctors or pharmacies received or relied on any purported distributor marketing materials. Plaintiffs’ answer to this is to say that “it makes no difference *which* doctors relied on what with respect to which prescriptions[.]” Pls. Memo at 21. But these experts lack reliable opinions not because they cannot determine *which* doctors relied on distributor marketing materials—they lack reliable opinions because they cannot determine if *any* doctors relied on distributor marketing materials. Moreover, while these experts acknowledge that other factors may have caused an increase in prescribing, none could say whether Distributors’ alleged marketing was a legal or proximate cause of Plaintiffs’ alleged harm because, as each of them admitted, they did not weigh the causal role of these other factors in affecting levels of prescribing, and Plaintiffs do not contend otherwise.

Additionally, each expert fails to offer a relevant opinion that “fits” the facts of this case. This case centers on Cabell County and the City of Huntington, yet *none* of these experts focused analyses of Distributor marketing activities there. The record belies Plaintiffs’ claim otherwise.

For these reasons—each of which is a sufficient reason—this Court should exclude Lembke, Keyes, Kolodny, and Mohr from testifying on Distributor marketing causation.

## ARGUMENT

### **I. Lembke, Keyes, And Kolodny Are Not Qualified To Give Opinions On The Causative Effect Of Distributor Marketing.**

As Distributors explained in their opening papers, Lembke, Keyes, and Kolodny are not qualified to give an opinion on Distributors’ alleged marketing activities or the impact of those activities. An expert must have specialized expertise and experience in marketing to opine on marketing and its effects. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod.*

*Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 633, 638 (4th Cir. 2018) (affirming exclusion of expert statistician who “was simply not qualified to make determinations about which patients’ data should have alerted Pfizer to a possible association between its drug and diabetes” because he “readily admitted that he had no expertise in diabetes”); *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 13022172, at \*11 (S.D. Ohio Oct. 2, 2015), *aff’d*, 680 F. App’x 369 (6th Cir. 2017) (striking expert’s testimony regarding pharmaceutical manufacturer’s marketing because he “lacks marketing and regulatory expertise and therefore would not be an appropriate expert to opine” on manufacturer’s promotion)).

Plaintiffs do not dispute that neither Lembke, Keyes, nor Kolodny has any education, training, or experience in marketing. *See* Exhibit E, Lembke Dep. at 122:5–9, 124:8–10; Exhibit G, Kolodny Dep. at 198:25–199:11; Exhibit B, Keyes Report at 4. Plaintiffs do not even dispute the reasoning of Judge Polster’s MDL ruling that neither Lembke nor Keyes is qualified to opine on marketing causation. MDL Ruling at 11, 20. Plaintiffs instead argue that Judge Polster simply “did not have before him information” that shows these individuals are qualified. Pls. Memo at 8, 10. Plaintiffs’ argument, however, is belied by the record.

**Lembke.** Plaintiffs argue that Judge Polster “did not have before him information” about the research, interviews, and assessment of literature Lembke conducted in writing her book. Pls. Memo at 8. This is false. Judge Polster had this information before him—he simply found that it did not qualify Lembke as a marketing expert. As Judge Polster ruled, Lembke’s book shows “no specialized training or experience by Lembke in the field of pharmaceutical marketing and/or its effect on prescribing practices, or the field of economics.” MDL Ruling at 11. Judge Polster also expressly “reject[ed] Plaintiffs’ arguments that, because Lembke formed her opinions in part on her review and assessment of scientific literature on this topic, she is qualified to opine on

marketing.” MDL Ruling at 11 n.5. Judge Polster reasoned that “a person does not become an expert in an area *outside of her regular field* merely by ‘reading up’ for the specific purpose of testifying.” *Id.* (quoting *In re Welding Fume Prod. Liab. Litig.*, No. 1:03-cv-1700, MDL 1535, 2005 WL 1868046, at \*35 (N.D. Ohio Aug. 8, 2015)) (emphasis added). Plaintiffs do not even try to grapple with this settled principle.

Plaintiffs also argue that Judge Polster was not aware that “Dr. Lembke is deemed sufficiently qualified to teach on marketing as it pertains to the opioid epidemic at Stanford University ....” Pls. Memo at 8. Lembke does not teach a marketing class, however—she teaches a class on the opioid epidemic and claims to discuss marketing during one day of the class. Lembke Dep. at 123:8–17. The fact that Lembke mentions marketing in a class does not make her a marketing expert who can pass *Daubert* scrutiny. An expert must have specialized expertise and experience in marketing to opine on marketing and its effects in court. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d at 633, 638; *Rheinfrank*, 2015 WL 13022172, at \*11 (S.D. Ohio Oct. 2, 2015), *aff’d*, 680 F. App’x 369 (6th Cir. 2017). As Judge Polster recognized after a full review of Lembke’s qualifications, “Lembke is highly distinguished as a medical expert in the scientific disciplines of psychiatry, addiction, and pain” but she does not have “specialized training, knowledge, or experience in the field of pharmaceutical marketing[,]” and thus she is not qualified to testify as an expert on marketing. MDL Ruling at 11.

Plaintiffs next contend that it does not “appear that Judge Polster was aware that ... physicians with credentials similar to Dr. Lembke’s have published peer-reviewed articles in scientific publications assessing the causes of the opioid epidemic, including the role of pharmaceutical marketing in changing prescribing habits and increasing sales.” Pls. Memo at 8.

Plaintiffs are wrong as a matter of fact. Judge Polster knew what similar non-marketing experts have done. He simply found their activities to be inconsequential and insufficient to move the needle on the qualifications question as it pertained to Lembke. In fact, in briefing before Judge Polster, the plaintiffs pointed to the same article that Plaintiffs rely on here and argued that “a 2018 article published in *Pain Physician* was authored by several influential medical doctors affiliated with pain management centers, none of whom identified as ‘marketing’ experts.” MDL Doc. # 1868 at 7 at n.13. Judge Polster held that this fact does not qualify Lembke as a marketing expert—and for obvious reasons: the fact that *others* have published articles on the causes of the opioid epidemic cannot establish **Lembke** as a marketing expert; and merely publishing an article on the opioid epidemic does not qualify someone as a marketing expert. An expert requires “specialized training, knowledge, or experience in the field.” MDL Ruling at 11 and n.5.

**Keyes.** With respect to Keyes, too, Plaintiffs argue that Judge Polster did not know that “epidemiologists with the same credentials as Dr. Keyes have published studies about the role [of] opioid marketing in causing the opioid epidemic, making clear that marketing credential[s] are not required in order to offer the opinions at issue here.” Pls. Memo at 10. Plaintiffs also argue that Keyes has been working hard to build up her qualifications by reading the literature and performing an epidemiological analysis of it. *Id.* at 10–11. But *Daubert* does not recognize expertise that is developed overnight for purposes of rendering a litigation opinion. MDL Ruling at 11 n.5. In any event, Keyes can review all of the literature in the world and it will not change the fact that her education and experience “does not show that her expertise in the scientific field of epidemiology includes the determination of marketing factors that contributed to the increased supply in prescription opioid.” *Id.* at 20. Here, moreover, her crash course in marketing did not include the very materials in dispute; Keyes admits that she “did not evaluate the specific marketing



materials.” Exhibit B, Keyes Report at 29. Keyes also has disclaimed knowledge of distributor marketing, stating, “I am aware that distributors engage in opioid marketing in general, and I don’t preclude that from occurring. But I’m – that’s not what I evaluate in my report, and I don’t offer an opinion on it.” Exhibit F, Keyes Dep. 279:2-6.

**Kolodny.** Kolodny has no better credentials to opine about marketing. Kolodny lacks an education in marketing (Kolodny Dep. at 198:25–199:11). Before he began working with the attorneys on this case, Kolodny “had no idea that distributors marketed, promoted, advertised opioids ....” *Id.* at 207:25–208:5; *see also* 205:5–14. Again, Kolodny’s attempt to “read up” about alleged distributor marketing at the request of Plaintiffs’ counsel does not make him an expert in the topic. MDL Ruling at 11 n.5 (quoting *In re Welding Fume Prod. Liab. Litig.*, 2005 WL 1868046, at \*35). Plaintiffs suggest that a defendant’s motion to exclude Kolodny in an Oklahoma trial was denied (Pls. Memo at 12), but the Oklahoma court’s one-page order—in a case involving only manufacturers—did not validate (or even address) Kolodny’s marketing credentials (*see* Pls. Ex. I & J). The bottom line is that Kolodny’s lack of specialized expertise on distributor marketing prevents him from testifying as an expert on the subject.

## **II. Lembke, Keyes, Kolodny, And Mohr Fail To Offer Admissible Expert Opinions On Distributor Marketing Causation.**

The Court need go no further than the lack of qualification to exclude the marketing-related opinions of Lembke, Keyes and Kolodny. Nonetheless, their opinions are flawed for additional reasons beyond the lack of qualification: **(A)** each of these individuals fails to offer an opinion based on a reliable methodology that Distributors’ so-called marketing activities affected or impacted physician prescribing; and **(B)** each fails to offer a relevant opinion that “fits” the facts of this case. These flaws also preclude Mohr’s marketing related opinions.

**A. Plaintiffs’ Experts Fail To Offer Reliable Opinions That Distributors’ Alleged Marketing Activities Affected Physician Prescribing.**

“A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249–50 (4th Cir. 1999) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–93 (1993)). None of these experts base their opinions on scientific, technical, or other specialized knowledge.

**First**, none of these experts identifies any marketing activities *by Distributors* (as opposed to manufacturers) that went directly to doctors or other healthcare prescribers. For instance, Keyes stated that “the materials that I have seen on marketing to physicians has been -- has been with regard to *manufacturers*.” Keyes Dep. at 283:24-284:14 (emphasis added). Plaintiffs do not—because they cannot—contend otherwise.

**Second**, none of these experts did *anything* to determine if doctors received or relied on any purported distributor marketing materials. They do not know whether (i) any Distributor disseminated any marketing material or (ii) whether any doctors saw any such marketing materials (much less whether any doctors relied on the materials in writing any opioid prescription). Lembke Dep. at 171:19–172:1; 172:20–23; 297:4–9; Keyes Dep. at 20:8-11, 143:9-10; Kolodny Dep. at 261:3–14; Exhibit H, Mohr Dep. at 140:2-6, 156:1-6, 17-22. These two steps are the necessary *first steps* in any reliable analysis of whether Distributors’ purported marketing affected the volume of opioids distributed to Cabell/Huntington. But, admittedly, the experts did not take these beginner steps.

Plaintiffs argue instead that the Court should not concern itself with this deficiency because “Plaintiffs need only show that Defendants’ conduct increased the supply of opioid[s] within their jurisdictions; it makes no difference *which* doctors relied on what with respect to which

prescriptions[.]” Pls. Memo at 21. But the experts do not know and cannot say for certain that *any* doctor—even a single one, let alone one with in the relevant jurisdictions—relied on distributor marketing materials. Lembke Dep. at 171:19–172:1; 172:20–23; 297:4–9; Keyes Dep. at 20:8–11, 143:9–10; Kolodny Dep. at 261:3–14; Mohr Dep. at 140:2–6, 156:1–6, 17–22. For them to opine that Defendants’ marketing conduct increased the volume of opioids is pure speculation. Their opinion is not grounded in any methodology that proceeds from (A) the facts about what materials were disseminated, by what means, at what times, and to what persons, to (B) some measurement of the effects of different materials and messages, if any, to (C) a causal conclusion. Thus, Lembke, Keyes, Kolodny and Mohr should be precluded from giving any opinion on marketing causation. *See In re Actos® (Pioglitazone) Prod. Liab. Litig.*, No. 6:11-MD-2299, 2014 WL 12653759, at \*13 (W.D. La. Jan. 14, 2014) (excluding marketing causation opinion because expert laid no foundation for knowing “what a physician or consumer *actually might have known or done*” and that finding that “what a doctor or consumer *might actually* have believed or *actually done* is, without question, outside her purview”).

**Third**, while these experts now conveniently opine for the first time that distributor marketing caused an increase in the prescribing of opioids, they acknowledge that other actors also caused an increase in prescribing—most prominently, the pharmaceutical manufacturers, whose deceptive marketing campaign Plaintiffs allege (in the Complaint, Amended Complaint, and Second and Third Amended Complaints) was the sole cause of increased prescribing. Yet, none of the experts weighed the causal role of these other factors in affecting levels of prescribing. *See* Mohr Dep. at 125:21–23, 126:4–10; Lembke Dep. at 101:20–102:8, 103:6–8, 104:19–23, 152:18–154:9, 230:2–24; Kolodny Dep. at 202:23–204:14, 207:5–12, 282:6–283:5, 314:14–316:10, Andrew Kolodny, Statement for the Record (Jan. 17, 2018); Keyes Dep. at 276:4–7. As

this Court has held, an expert opinion cannot pass muster under Rule 702 and *Daubert* unless the expert takes account of factors that may undermine the reliability of his or her opinions. *See Salazar v. United States*, No. CIV. A. 5:01-0617, 2003 WL 25695854, at \*3 (S.D.W. Va. Feb. 18, 2003) (Faber, J.) (excluding expert who “did not account for a possible alternative factual situation which would, if true, significantly affect the reliability of his opinion”); *Koger v. Norfolk S. Ry. Co.*, No. CIV.A. 1:08-0909, 2010 WL 692842, at \*4 (S.D.W. Va. Feb. 23, 2010) (Faber, J.) (excluding expert who “despite acknowledging the significance of personal attributes in an analysis of this kind, ... did not consider these factors in reaching his conclusions”).

Plaintiffs argue that their experts are not required to account for alternative causes because they need only show that Distributors’ conduct was “a proximate cause” of Plaintiffs’ injury. Pls. Memo at 22. Even apart from Plaintiffs’ strained reading of the legal authorities, this contention misses the point. Once the experts acknowledge alternative causes, they cannot offer a reliable causation opinion without accounting for those causes. In other words, Plaintiffs’ experts cannot say that something is even *a* cause if they failed to consider other known alternative causes. *See Salazar*, 2003 WL 25695854, at \*3; *Koger*, 2010 WL 692842, at \*4.

Indeed, Dr. Mohr specifically acknowledged that she had not evaluated these alternative causes. As Mohr testified, she “can’t disentangle the total industry’s [e]ffect to look at distributors.” Mohr Dep. at 125:21-23. According to Mohr, “[t]hat would be an econometric study that would take some time to sort out. That was not in the scope of my task.” *Id.* at 126:4-10.

#### **B. Plaintiffs’ Experts Fail To Offer Relevant Opinions That Fit This Case.**

Expert testimony is not admissible under *Daubert* unless it is relevant. Expert testimony must have “a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Daubert*, 509 U.S. at 592. “The consideration has been aptly described ... as one of ‘fit.’” *Id.* at 591. Lembke, Keyes, Kolodny and Mohr do not offer relevant opinions that fit this case.

This case is about Cabell County and the City of Huntington, yet *none* of these experts focused their analyses on Cabell County and the City of Huntington. Any suggestion to the contrary is flatly contradicted by the record.

**Lembke.** Plaintiffs point to Lembke’s statement in her report that “Cabell County/City of Huntington in particular, were among the hardest hit[] by the oversupply of opioid pain relievers, igniting the opioid wildfire that continues to the present.” Expert App’x, Dkt. # 1097, at Ex. 7.a (Lembke Report) (Appendix III, 237–251). But that statement says nothing at all about marketing or even attempts to causally connect purported marketing activities by Distributors to the alleged oversupply in Cabell County or the City of Huntington. In fact, Lembke admitted that she is unaware of any doctor, pharmacy, or patient in Cabell County or the City of Huntington actually receiving (much less relying upon) the supposed marketing materials she reviewed. Lembke Dep. at 102:19–23; 128:3–7; 131:19–132:4; 146:24–147:4; 262:21–263:7; 273:4–9; 273:24–274:5; 275:3–6; 279:4–9; 281:6–9; 284:3–6; 296:23–297:9; 299:22–300:2. Nor has she reviewed any orders that the distributors in this case shipped to pharmacies in Cabell County or the City of Huntington, *id.* at 161:5–8, let alone determined whether any of the pharmacies were influenced by Distributors’ alleged marketing.

**Keyes.** Plaintiffs state that “Dr. Keyes’ review of the localized data found that as the volume of prescription opioids flooded into Plaintiffs’ communities, the overdose deaths substantially increased.” Pls. Memo at 24 (citing Keyes Report at 35). But, again, that opinion does not relate to marketing. Nor could it, as Keyes admitted that she is unaware of any direct marketing to physicians by Distributors in Cabell County or the City of Huntington, Keyes Dep. at 282:9–12, or even any direct marketing to physicians by distributors in West Virginia generally,

*id.* at 282:5-8. As Keyes admits, “the materials that I have seen on marketing to physicians has been -- has been with regard to *manufacturers*.” *Id.* at 284:5-7 (emphasis added).

**Kolodny.** Plaintiffs point to Kolodny’s statement that “West Virginia has been accurately characterized as ‘ground zero’ in the opioid crisis” and his citation to a House Energy and Commerce Committee Report finding that “the sudden influx of prescription opioids, leading to resulting increases in abuse and addiction, has had profound effects on West Virginia.” Exhibit C, Kolodny Report at 20. But, here again, Plaintiffs point to statements that have nothing to do with marketing. While Kolodny may hold the opinion that West Virginia is “ground zero,” that says nothing about the role any alleged marketing by a distributor might have played in making West Virginia “ground zero.” Nor could Kolodny offer any such opinion. He does not know whether any of the supposed marketing materials he analyzed were actually disseminated in Cabell County or even West Virginia, Kolodny Dep. at 284:14–285:2, he cannot point to any evidence that any pharmacist in Cabell County or the City of Huntington ever received or considered the marketing materials he considered in deciding whether to make a purchase, *id.* at 285:3–286:3, and he has not conducted any survey or study on whether pharmacists—in Cabell County and the City of Huntington or otherwise—considered the materials he analyzed in deciding whether to make purchase, *id.* at 286:4–23. And Plaintiffs do not contend otherwise.

**Mohr.** Plaintiffs do not even argue that Mohr’s opinions are a “fit” and thus the Court can exclude Mohr on this basis alone. Mohr undisputedly cannot point to any “marketing” materials that Distributors sent to Cabell County or the City of Huntington. Mohr Dep. at 132:24-133:5. Similarly, she has not considered whether any supposed “marketing” by Distributors had any effect on the manner in which pharmacies in Cabell County and the City of Huntington placed orders for prescription opioids. Mohr Dep. at 31:23-32:5; 34:24-35:3. Plaintiffs do not try to argue

otherwise. And while Mohr attempts to conflate Distributor communications to pharmacies as “marketing,” she did not distinguish between communications relating to opioids versus other non-opioid medications. As Mohr stated, “my task was to talk about the marketing services generally, and I did not divide them by which were opioid specific compared to other types of products.” Mohr Dep. 239:7-10. As such, Mohr is unable to offer any opinion that any activities by Distributors relating to their supply of medications to pharmacies in Cabell County or the City of Huntington resulted in an increase of orders for opioids by those pharmacies. *Id.* at 105:22-106:1; 160:6-11.

For these reasons, Lembke, Keyes, Kolodny and Mohr do not offer relevant opinions that fit this case.

### **III. Other Experts Who Have Made Statements About Distributor Marketing Causation Should Be Precluded From Testifying On The Topic.**

As Distributors explain in their opening papers, other experts who do not opine on Distributor marketing nonetheless have made gratuitous statements on the topic during their depositions. These individuals lack qualifications and have no basis to claim a reliable or relevant opinion on the topic.

Plaintiffs concede that “Dr. [Gordon] Smith is not offering a distributor ‘marketing causation’ opinion” and thus cannot testify as to marketing causation at trial. Pls. Memo at 25. Plaintiffs, however, contend that their other expert who made stray comments about marketing causation—Dr. David Courtwright—actually does have a reliable and relevant opinion on distributor marketing causation. *See id.* But Courtwright—like Lembke, Keyes, and Kolodny—is not qualified to offer a marketing causation opinion. He is a historian who has no education or experience in marketing. Exhibit I, Courtwright Dep at 33:14–20; 96:20–97:5. Courtwright admits that “I don’t consider myself to be an expert in marketing in general, no.” *Id.* at 97:4–5.

In any event, like Mohr, Courtwright never ties his ruminations on what might constitute distributor marketing to anything about causation, and thus cannot provide a relevant opinion on the topic. For these reasons, this Court also should preclude Courtwright from offering any opinion on marketing causation.

### CONCLUSION

This Court should exclude Lembke, Keyes, Kolodny, and Mohr from testifying on the causative effect of distributor marketing. It also should also exclude Courtwright and Smith from incorporating their gratuitous statements about marketing into any testimony they give in this case at trial.

Dated: October 30, 2020

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**CERTIFICATE OF SERVICE**

The undersigned counsel hereby certifies that on this 30th day of October, 2020, the foregoing *Reply in Support of Defendants' Motion to Exclude the Marketing Opinions of Anna Lembke, Katherine Keyes, Andrew Kolodny, and Jakki Mohr* was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Gretchen M. Callas